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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/685,010	10/05/2000	Eva A. Turley	910130.401C1	5697

7590 12/24/2003

Mary Ann Dillahunty, Esq.
Burns, Doane, Swecker & Mathis, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

EXAMINER	
LIU, SAMUEL W	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/685,010	TURLEY ET AL.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2003 and 03 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39 and 40* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the claims

Claims 39 and 40 are pending.

Applicants' pre-amendment filed 11 December 2002, which cancels claim 27, adds claim 38, and amends claims 1-4, 7-8, 10 and 21, and amendment filed 3 September 2003, which cancels claims 1-36 and 38 and adds claims 39-40, have been entered. Also, Applicants' requests for extension of time of: two months (filed 9 April 2001), three months (filed 24 May 2001), two months (filed 11 December 2002), and three months (filed 3 September 2003) have been entered.

Election/Restrictions

Applicant's election (see the response filed 3 September 2003) of Group III, claims 39-40 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Therefore, the elected claims 39 and 40 are under examination to the extent that they are drawn to the elected invention.

Specification/Claim/ Objections

The disclosure is objected to because of the following informalities:

(1) In page 3, line 5, "HA", line 8 "RHAMM" should be spelled out in full at the first instance of use. See also page 5, line 3, "AP-1"; page 10, line 26, "PL" and "FN", line 28, "GAPDH" and "CDNAS"; page 11, line 3, "IL-1" and "TNF"; page 12, line 4, "LZP", line 11, "HFF", line 24, "BAL"; page 13, line "ERK *kinase*", line, "FACS"; page 26, line 15, "SSPE"

and SDS"; page 28, line "PCR"; page 34, line 16, "CHO"; page 35, line 17, "MMTV", "LTR", "RSV", and "SV40", and line 26, "IPTG"; page 55, line 15, "AIDS" and line 23, UV"; page 60, line 28, "PDEF", "FGF" and "TGF"; page 71, line 27, "EDTA"; page 73, line 9, "MAP"; page 74, line 5, "GST"; page 76, line 3, "DTT"; page 81, line 29, "SDS_PAGE"; page 88, line 23, "BSA" and "PBS"; page 93, line 15, "FBS"; page 94, line 7, "CCD"; page 96, line 8, "RIPA"; page 100, line 4, "RA", line 8, "HBSS" and line 14, "FITC"; page 101, line 28, "ABC". Page 102, line 1, "DAB"; page 105, line 12, "RT-PCR"; page 107, line 22, "RT"; page 109, line 4, "CaP", line 5 "DMEM", and line 18, "HRP"; page 110, line 12, "MMP"; page 126, line 29"IDDM".

(2) In page 4, lines 4-5, "aa. 635-645 and aa. 657-666 RHAMM" should be changed to "amino acid residues 635-645 and amino acid residues 657-666 of human RHAMM".

(3) In page 8, line 1, "Nos." should be changed to "NOs:"; the same correction should be made throughout the specification.

(4) In page 9, line 10, "SEQ ID NO: 1-10" should be changed to "SEQ ID NOs: 1-10".

(5) In page 11, line 10, "RHAM" should be changed to "RHAMM".

(6) In page 12, line 13, "aa423-432" should be changed to "amino acid residues 423-432".

(7) In page 24, line 20, "(R" should be changed to "(R)".

(8) In page 63, line 12, "kd" should be changed to "kDa".

(9) In page 93, line 6, "9 AA" should be changed to "9 amino acid residues"; the same correction should be made throughout the specification.

(10) In page 109, line 7, "CO2" should be changed to "CO_2"; the same correction should

be made throughout the specification.

(11) In abstract, a period "." is omitted from the third to the last sentence.

(12) In claim 1, "HA" and "RHAMM" should be spelled out for the first time recitation in the claims.

(13) The abstract of the disclosure is objected to because the abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. Note that the abstract of the instant application contains more than 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. A single paragraph of 150 words or less commencing on a separate sheet following the claims is required. See MPEP § 608.01(b). The language should be clear and concise.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 recites "...which binds HA"; the recitation is unclear as to whether or not "HA" refers to dipeptide sequence (His-Ala), or "HA" tag, or a biopolymer. The dependent claim 40 is also included in the rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of an isolated polypeptide with a structurally defined Hyaluronan (HA)-binding motif, e.g., peptide consisting of 9 amino acids and has all structural characteristics disclosed in SEQ ID NO:28. Applicant is not in possession of any polypeptides comprising the BX7B (SEQ ID NO:28) sequence.

Note that many proteins or polypeptides comprising the BX7B structural motif, e.g., IαI protein, SPACR (a factor SialoProtein Associated with Cones and Rods), CD38, CDC37, P32 and CD44 etc. (see page 4587,the right column, Day, A. J. et al. (2002) *J. Biol. Chem.* 277, 4585-4588). The current claim language "comprising" is the open-ended; thereby the claimed composition encompass a large number of polypeptides, including chemical modified, recombinantly or genetically produced polypeptides, or/and any protein chimeras to which any heterologous polypeptide(s) is covalently linked. The specification does not describe the polypeptides mentioned above. The specification only describes SEQ ID NO:28 hat is a generic peptide sequence (see pages 5-7). Therefore, the skilled artisan cannot envision all the contemplated polypeptide sequence possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional

properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶ 1"Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

Given the lack of a written description of *any* additional representative species having the structural feature of SEQ ID NO:28, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative member of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claim Rejections - 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 39-40 are rejected under 35 U.S.C. 102 (b) as being anticipated by Turley, E. A. et al. (WO 9738098).

Turley et al. teach a peptide sequence KQKIKHVVK (residues 1-9 of SEQ ID NO:1, see page 8, line 21), which meets all of the structural characteristics of SEQ ID NO:28 (i.e., BX7B) set forth in the application claim 39. Note that "BX7B" sequence is defined by SEQ ID NO:28 as that the first and the last (9^{th}) residues are basic amino acids and residues 2-8 are any amino acids other than acidic residue(s)). The above mentioned peptide has hyaluronan-binding capability (see page 5, lines 9-12).

Thus, the Turley et al. teaching anticipates the current invention.

Claims 39-40 are rejected under 35 U.S.C. 102 (b) as being anticipated by Turley, E. A. (WO 9321312).

Turley discloses a hyaluronan-binding peptide motif (see the patent claims 11-12) reads on "BX7B" structural characteristics, i.e., the first and the last (9^{th}) residues are basic amino acids and residues 2-8 are any amino acids other than acidic residue(s)). Turley teaches (i) a RHAMM polypeptide comprising SEQ ID NO:3 that contains the "BX7B" motif (see Table 1 on page 45), (ii) the peptides consisting of "BX7B" motif", i.e., KIKHVVKLK and KLRSQLVKR (see the patent claims 16-17), and (iii) polypeptide comprising SEQ ID NO:4 (see Figure 17) which possesses the "BX7B" motif stated supra. Also, Turley teach the pharmaceutical composition comprising the peptide that comprises the "BX7B" motif, e.g., KIKHVVKLK (see the patent claims 27-29). Therefore, Turley's teachings anticipate claims 39 and 40 of the current application.

Provisional Rejection - Obviousness Type Double Patenting

Claims 39 and 40 of this application conflict with claims 1 and 2 of Application No. 09978309. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claims 39 and 40 are provisionally rejected under the judicially created doctrine of double patenting over claims 1 and 2 of Application No. 09978309. This is a provisional double patenting rejection because the conflicting claims have not in fact been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

Claims 1 and 2 of Application 09978309 claims the same subject matter as claims 39 and 40 of the instant application. Application No. 09978309 sets forth an isolated polypeptide comprising SEQ ID NO:74 that comprise the sequence, i.e., KIKHVVKLK that consists of residues 196-204 of SEQ ID NO:74, which reads on SEQ ID NO: 28 of the instant application, and teaches a pharmaceutical composition comprising the polypeptide thereof.

Therefore, the instant application and copending application claims are obvious variation.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703 308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

SWL

Samuel Wei Liu, Ph.D.

December 19, 2003

ROBERT A. WAX
PRIMARY EXAMINER